K093258

Helix Medical, LLC
510(k) Summary
Blom-Singer® Indwelling TEP Occluder

I NAME OF SUBMITTER

Helix Medical, LLC
1110 Mark Ave.
Carpinteria, CA 93013
Contact Person: Cynthia Anderson
Establishment Registration Number: 2025182

MAR - 3 2010

II DEVICE NAME AND CLASSIFICATION

Proprietary Name: Blom-Singer® Indwelling TEP Occluder
Common or Usual Name: TEP Occluder

Class II, 21 CFR 874.3730
The Blom-Singer Indwelling TEP Occluder is neither a life-supporting nor a life-sustaining device. It is not considered an implant.

III PREDICATE DEVICES

K932120, Blom-Singer Indwelling Low Pressure Voice Prosthesis, April 15, 1994

K812982, Blom-Singer Dummy Voice Prosthesis with Retention Collar, November 24, 1981

Related accessories being provided with product:

- inserter stick
- flushing device
- flange introducer
- gel caps
- lubricant

IV DESCRIPTION

The Blom-Singer Indwelling TEP Occluder is designed to provide fistula maintenance while preventing leakage of liquids from the esophagus into the trachea after total laryngectomy. The Indwelling TEP Occluder has been modified from its predicate devices by the inclusion of the Indwelling Low Pressure Voice Prosthesis design, and is now available in 16 and 20 fr. Sizes. In addition, this device will be offered in a large esophageal flange version.

This version will be identical except for an esophageal flange which is greater in diameter to deter leakage around the device in individuals with unique physiology. These devices are manufactured from medical grade silicone and are latex-free.

V INTENDED USE

The Blom-Singer Indwelling TEP Occluder is indicated for anterograde placement in and maintenance of the TE puncture following total laryngectomy when placement, or replacement, of an indwelling occluder is performed by a qualified, trained medical professional. This device is for use with healed, intact tracheoesophageal puncture fistulas only.

VI TECHNOLOGICAL REQUIREMENTS

The Blom-Singer® Indwelling TEP Occluder is designed to provide fistula maintenance while preventing leakage of liquids from the esophagus into the trachea after total laryngectomy. Voicing is not possible with this device. This device is for use with healed, intact tracheoesophageal puncture fistulas only and is placed by the clinician using an anterograde method. A gel cap insertion system facilitates placement. The use of an indwelling device means that routine removal and cleaning by the patient is not necessary.

There are two predicate devices to which equivalence of this device is claimed, both are manufactured from medical grade silicone and are latex-free. The first, Blom-Singer Indwelling Low Pressure Voice Prosthesis, provides fistula maintenance while preventing leakage of liquids from the esophagus into the trachea after total laryngectomy. This device is intended for voicing. Anterograde placement is performed by a clinician in a surgically-created fistula between the trachea and esophagus.

The Blom-Singer Dummy Duckbill with Retention Collar (now known as Blom-Singer TEP Occluder) is designed to provide fistula maintenance and prevent leakage of liquids from the esophagus into the trachea after total laryngectomy. It is not intended for voicing and does not require placement by a clinician.

Functional equivalency tests have been performed on the Blom-Singer devices which demonstrate the equivalency of device performance with the three designs. Non-clinical tests referenced for a determination of substantial equivalence are Pressure Decay, Flange Retention Force, and Gel cap Insertion method. The conclusions drawn from the nonclinical tests demonstrate that the device is safe, as effective, and performs as well or better than the predicate devices.

Accessory Devices:

- flange introducer
- gel caps
- inserter sticks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 3 2010

Helix Medical, LLC
c/o Ms. Cynthia Anderson
Regulatory Affairs
1110 Mark Ave.
Carpinteria, CA 93013

Re: K093258
Trade/Device Name: Blom-Singer Indwelling TEP Occluder
Regulation Number: 21 CFR 874.3730
Regulation Name: Laryngeal prosthesis (Taub design)
Regulatory Class: Class II
Product Code: EWL
Dated: January 28, 2010
Received: January 29, 2010

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

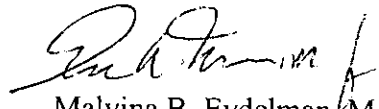
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093258

Indications for Use Statement

510(k) Number: K093258/S002

Device Name: Blom-Singer Indwelling TEP Occluder

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE, IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 DFR 801.109)

Daniel C Clapper

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K093258